

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application, as proposed to be amended, in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.116, are respectfully requested.

Status and Summary of Amendments

By the foregoing amendment, applicants propose to cancel Claims 5-7, 30 and 44-46, which have been previously withdrawn from consideration. Applicants further propose to add Claims 93 and 94, previously presented in applicants' June 22, 2004 Supplemental Amendment but not entered. It is believed that the Examiner erred in refusing to enter these claims. It was clear from the Remarks section of applicants' June 22, 2004 filing, that the Supplemental Amendment did not further respond to the previous Office Action but merely added two claims to round out the protection sought. The amendment was filed more than a month prior to issuance of the final rejection and courtesy copies of the amendment were additionally faxed to the Examiner. Thus, the submission of these claims was timely and they should be entered.

Upon entry of this amendment, Claims 1-4, 8-18, 20-29, 31-43, 47-50, 93 and 94 will be in this application.

Applicants reserve the right to file one or more divisional or other continuing applications on the canceled non-elected subject matter.

Previous Rejection Under 35 U.S.C. § 112, Second Paragraph – Indefiniteness

The withdrawal of the 35 U.S.C. § 112 rejections is noted, with appreciation.

Rejection Under 35 U.S.C. § 103(a) – Lochhead in View of the Handbook

Claims 1-4, 8-10, 15-18, 20-29, 40-43, 47-48, and 50 have been rejected under 35 U.S.C. § 103(a) as purportedly obvious over European Patent Application 0 268 164 to Lochhead *et al.* ("Lochhead") in view of the Handbook of Cosmetic Science and Technology ("Handbook"). See *Official Action mailed July 28, 2004, Pages 2-4*. This rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. See M.P.E.P. § 2142. Applicants respectfully assert that even if one were motivated to combine Lochhead with the Handbook, a notion applicants do no concede, such a combination would not establish a *prima facie* case of obviousness of the rejected claims because the cited publications do not disclose or suggest all of the claim limitations.

Specifically, all of the independent Claims (1, 41, 49, 50, 93 and 94, of which Claims 1, 41 and 50 are rejected) specify that the biologically active agent (A) is in micronized particulate state and is non-solubilized in said emulsion, wherein at least 80%, numerically, of said micronized particles have diameters ranging from 1 to 10 μm , and at least 50%, also numerically, of said micronized particles have diameters

of less than 5 μm . The size of the particles disclosed in Lochhead is directed to the size of the dispersed phase (oil) of the emulsion, whereas in applicants' invention, the size of the particles is directed to the micronized and non-solubilized biologically active agent particles independently of the size of the oily droplets of the emulsion.

The Examiner disagrees with applicants' characterization of Lochhead and points to page 8, lines 5-7 of Lochhead as supporting her view. With all due respect, it is submitted that the Examiner is taking these lines of Lochhead out of context. On page 2 of Lochhead, in the Background of the Invention, second paragraph, Lochhead clearly teaches "Oil-in-water emulsions contain discrete droplets or particles of oil in a continuous water phase." (Emphasis added). Further, in the Summary of the Invention on page 2, Lochhead notes that his oil-in-water emulsions are designed to be stable at a pH less than 6 and to break when they come into contact with an electrolyte, such as in perspiration.

Thus, reading page 8 of Lochhead in the context of his invention, including the Background of the Invention which he describes, means that he is talking about the particle sizes of the oil droplets in the art and the much larger oil droplets of his invention. Lochhead teaches nothing about the size of micronized particles of a biologically active agent which is not solubilized in the aqueous phase or in the oil phase. No such non-solubilized active agent appears to be present in Lochhead or indeed in any reference cited by the examiner.

The Handbook does not cure the deficiencies of Lochhead, as this, too, does not refer to applicants' micronized, non-solubilized biologically active agent particles, but to the emulsion particle size. The Handbook is cited to show that smaller particle

size will lead to a greater interfacial area and, hence, a higher propensity to form a structure and further teaches that the rate of phase separation can be reduced by reducing the dispersed phase particle size. But the object of the Lochhead invention is to provide a fast-breaking composition, and his composition has a much larger oil droplet particle size than conventional oil-in-water emulsions. One of ordinary skill would therefore not be motivated to try to make Lochhead's oil droplets smaller, for fear of losing the very properties which characterize the Lochhead invention. It is also logical to assume from Lochhead that the identity of his polymer is responsible for the size of his droplets. Thus, one of ordinary skill has no motivation to combine Lochhead with the Handbook.

Furthermore, the combination of Lochhead and the Handbook fails to disclose or suggest at least the size of the micronized, non-solubilized biologically active agent particles of applicants' invention. Applicants therefore submit a *prima facie* case of obviousness has not, and cannot, be made out. Accordingly, applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of Claims 1-4, 8-10, 15-18, 20-29, 40-43, 47-48, and 50.

Rejection Under 35 U.S.C. § 103(a) – Lochhead in View of the Handbook in Further View of Pisson

Claims 11-12 and 37-39 have been rejected under 35 U.S.C. § 103(a) as purportedly obvious over Lochhead in view of the Handbook in further view of U.S. Patent No. 5,882,633 to Pisson et al. ("Pisson"). See *Official Action mailed July 28, 2004, Pages 2-3*. This rejection is respectfully traversed.

As explained above, applicants maintain that the combination of Lochhead and the Handbook fail to establish a *prima facie* case of obviousness against any of the pending claims. Pisson does not cure the deficiencies of Lochhead and the Handbook. Accordingly, applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of Claims 11-12 and 37-39 over Lochhead in view of the Handbook in further view of Pisson.

Rejection Under 35 U.S.C. § 103(a) – Lochhead in View of the Handbook in Further View of Pisson in Further View of Kaplan

Claims 13-14 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious over Lochhead in view of the Handbook in further view of Pisson and further in view of U.S. Patent No. 5,916,543 to Kaplan *et al.* ("Kaplan"). See *Official Action mailed July 28, 2004, Page 3*. This rejection is respectfully traversed.

As explained above, applicants maintain that the combination of Lochhead and the Handbook fail to establish a *prima facie* case of obviousness against any of the pending claims. As with Pisson, Kaplan does not cure the deficiencies of Lochhead and the Handbook. Accordingly, applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of Claims 13-14 over Lochhead in view of the Handbook in further view of Pisson and Kaplan.

Rejection Under 35 U.S.C. § 103(a) – Lochhead in View of the Handbook in Further View of Kim

Claims 31-36 have been rejected under 35 U.S.C. § 103(a) as purportedly obvious over Lochhead in view of the Handbook in further view of U.S. Patent No. 5,980,939 to Kim *et al.* ("Kim"). See *Official Action mailed July 28, 2004, Page 3*. This rejection is respectfully traversed.

As explained above, applicants maintain that the combination of Lochhead and the Handbook fail to establish a *prima facie* case of obviousness against any of the pending claims. Kim does not cure the deficiencies of Lochhead and the Handbook. Accordingly, applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of Claims 31-36 over Lochhead in view of the Handbook in further view of Kim.

Non-Rejected Claim

It is respectfully pointed out that there is no record rejection of Claim 49. Although the Office Action Summary indicates it is rejected, there is no rejection of this claim in the body of the Action. Further, Claims 93-94, which were not entered previously, have not been rejected. All of these claims are distinguished over the art for at least the reasons set forth above.

CONCLUSION

From the foregoing, further and favorable consideration in the form of a Notice of Allowance is respectfully requested and earnestly solicited.

In the event that there are any questions relating to this response, or the application in general, it would be greatly appreciated if the Examiner would

telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,
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